IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Group Art Unit: 1653
	)	
Rainer K. Brachmann	)	Examiner: Karen C. Carlson
	)	
Serial No.: 10/500,155	)	Docket No. 004255.00027
	)	
Filed: October 29, 2004	)	
	)	

For: GLOBAL SUPPRESSORS OF P53 MUTATIONS

RESPONSE TO OFFICE ACTION

Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

In response to the Office Action mailed July 27, 2006, applicant requests reconsideration of the patentability of the claims.

No fee accompanies this paper. If one is necessary, please charge our Deposit Account No. 19-0733.

Abstract

A copy of the abstract on a separate sheet is enclosed at Appendix 1.

Rejection of Claims 1-36 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-36 are rejected as indefinite for failure to provide an amino acid sequence of wild-type p53. The specifically named mutations recited in the claims are therefore allegedly unsearchable. This rejection is respectfully traversed.

The tumor suppressor protein p53 was well known in the art as of the effective filing date of January 16, 2002. *See,* the revision history of NP_000537 (Appendix 2)

and the annotated report of NP_000537 as it existed in GenPept, NCBI on the effective filing date (Appendix 3). Protein p53 was known to be a 393 amino acid residue protein. *See* reference mark A on Appendix 3. Each of references 40-49 (reference mark B) is cited as teaching residues 1 to 393. References 40-49 range in publication dates from 1984 to 1991. These exhibits demonstrate that p53 and its sequence were well known in the art.

Each of the mutations recited in the claims is identified by the residue number and the wild-type amino acid residue. For example, claim 1 recites T81S which is a mutation that has a serine for threonine substitution at residue 81. Referring to NP_000537 as it existed on the effective filing date, one indeed finds a threonine at residue 81. (Reference mark C on Appendix 3). Because the sequence of p53 was known in the art for almost 20 years as of the effective filing date, the claims' recitations of particular residues in the sequence is neither indefinite nor unclear.

Further evidence that the p53 protein sequence was known in the art is found in the specification in the reference list at page 31. Kaghad et al. is cited . Kaghad discloses the wild-type amino acid sequence of p53 at Figure 1a. *See* Appendix 4.

The law does not require that a sequence that is known in the art be reported in the specification. "The Board's requirement that these [known] sequences must be analyzed and reported in the specification does not add descriptive substance." *Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005). This accords with the more general settled law that a patent need not teach, and preferably omits, what is well known in the art." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed Cir. 1986).

In view of the state of the art and the references in the specification, both of which included the full 393 amino acid sequence of wild-type p53 protein, the claims which

recite individual residues of wild-type p53 by reference number and amino acid are clear and definite. The claims "reasonably apprise those skilled in the art both of the utilization and scope of the invention." *Hybritech, supra,* at 1385.

The claims are clear and definite as they stand. Withdrawal of this rejection is therefore respectfully requested.

Respectfully submitted,

Date: October 20, 2006

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